REMARKS/ARGUMENTS

Claims 1-42 were pending. Claims 37-42 are withdrawn from consideration. Claims 1, 12, 22, 28 and 34 are amended. No new matter has been added.

Applicant's pending claims recite drug dosage forms that include a compound susceptible to moisture induced degradation, e.g., thyroid hormone, and an excipient that are prepared by compressing the dosage forms at low pressure, e.g., up to 5,000 psi/g. It has been found that increasingly stable compositions containing compounds susceptible to moisture induced degradation are achieved by compacting drug dosage forms at low pressures. During compaction at elevated pressures, residual moisture is liberated from excipients and then reacts with (degrades) the compound susceptible to moisture induced degradation. Preparing drug dosage forms using low compression techniques as recited in the pending claims reduces undesirable moisture induced degradation by limiting the amount of equilibrium moisture available to react with the thyroid hormone.

Claim Rejection – 35 U.S.C. §102(b)

In the Office action claims 1-11, and 34-36 have been rejected under 35 U.S.C. §102(b) as allegedly being unpatentable over U.S. Patent No. 4,389,393 to Schor et al. ("the Schor patent"). This rejection is respectfully traversed as the Schor patent does not teach every element and limitation of the claimed invention.

The Schor patent teaches a carrier base material and a therapeutically active medicament that is compressed into a solid unit dosage form. The Schor patent teaches forming the solid unit dosage form at "compression pressures of 2000 to 16000 psi," (Col 5, lines 36-37), a unit of measure *independent of the mass* of the dosage form. However, this

teaching of a compression pressure is meaningless compared claims 1-11, and 34-36, as amended, because the claims recite compaction pressures in pounds per square inch *per gram*, i.e., units of measure dependent on the mass of the unit dosage form being compressed.

It is clear that the Schor patent does not teach compositions prepared using low compression pressures of up to 5000 psi/g when the same system of measurement is used (psi/g). For example, Example 6 describes preparation of a 717 mg aspirin tablets compressed at 5000 psi. A compression pressure of 5000 psi applied to a 717 mg tablet yields a compression pressure of roughly 6973.5 psi/gram (5000 psi /.717grams). Similarly, Examples 3 & 4 describe preparation of a 722.5 mg aspirin tablets compressed at 4000 psi, i.e., 5536 psi/gram. The Schor patent simply does not teach unit dosage forms prepared by low pressure compression techniques that reduce the undesirable moisture induced degradation of a thyroid hormone as recited in the pending claims. Indeed, the Schor patent does not even recognize the benefits of utilizing low compression techniques to prepare drug dosage forms. Therefore, the Schor patent does not teach unit dosage forms prepared by low pressure compression techniques that reduce the undesirable moisture induced degradation of a thyroid hormone as recited in claims 1-11, and 34-36. Accordingly, since the Schor patent does not teach all of the elements of Applicant's claims 1-11, and 34-36, withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

Claim Rejection – 35 U.S.C. §103(a)

Claims 12-33 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,051,406 to Satoh ("the Satoh patent"). Applicant

traverses this rejection because the cited references do not teach or suggest the claimed invention.

The Satoh patent teaches pharmaceutical compositions composed of a drug, albumin, and a fatty oil. The drug is dissolved in the fatty oil during preparation. The Satoh patent does not teach drug dosage forms prepared by low pressure compression techniques that reduce the undesirable moisture induced degradation of a thyroid hormone as recited in claims 12-33, as amended. Indeed, the Satoh patent does not teach any compression pressures for preparation of dosage forms.

Further, there is no recognition of the benefits of utilizing low compression techniques to prepare drug dosage forms. Without such a teaching or suggestion, the present claims cannot be found to be obvious in view of the Satoh patent. To establish a prima facie case of obviousness, all limitations set forth in a patent claim must be taught or suggested in the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

CONCLUSION

Applicant believes that the foregoing is a full and complete response to the Office Action of record. Accordingly, an early and favorable reconsideration of the rejections and allowance of all of pending claims 1-36 are respectfully requested.

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